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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To whom it may concern:

Enclosed are 2 copies of written comments for the public meeting on 'Bare-Hand Contact of Ready-to-Eat Foods' on September 21, 1999 (Docket no. 99N-0438).

Thank you.

Sincerely,

Amy C. Lee Wong
Associate Professor

DOCKET NO. 99N-0438 (Bare Hand Contact of Ready-to-Eat Foods)

Survival and inactivation of foodborne pathogens on hands and gloves

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A major cause of foodborne diseases is contamination by **food** handlers. In addition to practicing good personal hygiene, the use of gloves has been advocated to prevent pathogen contamination of food. We initiated a study to determine: (a) efficacy of hand-washing on inactivation of four common **foodborne** pathogens, *Salmonella enteritidis, Escherichia coli 0* 157:H7, *Staphylococcus aureus,* and *Bacillus* cereus; (b) pathogen survival on hands versus gloves; and (c) potential for pathogen transfer from hands and gloves.

hand-washing

For hand-washing experiments, 4-5 subjects were used for each parameter tested. Each experiment was conducted at least twice. Ten microliters containing about 10^3 CFUs of a given pathogen were inoculated onto each of a subject's eight fingertips, excluding the thumbs. The inoculum was immediately spread evenly on each fingertip using the side of **a** pipette tip. After air drying for two minutes, each finger was allowed to touch with a rolling action the surface of an agar plate. The touched area was spread with a sterile spreader and the CFUs counted following incubating of the plate. This provided an estimation of the number of organisms that can be transferred from a contaminated finger before hand-washing.

To test the efficacy of pathogen removal by washing with soap, inoculated hands were washed for 20 seconds (per FDA Food Code) with 3 ml of an antibacterial soap and rinsed with water. Subjects dried their hands with two disposable paper towels before touching agar plates for bacterial enumeration. To test the effect of mechanical action alone on pathogen removal, inoculated hands were washed with water for 20 seconds, dried, and bacterial numbers were enumerated. The efficacy of an alcohol-based hand sanitizer was also evaluated. 3 ml of the sanitizer was applied to both hands, which were rubbed together until dry. The same hand-washing procedures were applied to uninoculated hands to determine their effects on the normal flora.

Recovery of the inoculated pathogens before and after washing by various procedures is listed in Table 1. After inoculation and air drying for two minutes, 2.3 to 10.3% of the inoculum was recovered (or potentially transferable) when the fingers were touched to an agar plate. It was also noted that the percent recovered depended on the degree to which the inoculum had dried on the finger. Recovery was generally higher if the finger remained visibly moist after two minutes (data not shown). Washing with plain water, soap, or the hand sanitizer removed or inactivated all of the inoculated *S. enteritidis* and E. *coli* O157:H7, whereas 0.2 to 3.6% of the inoculated S. *aureus* or B. *cereus* could be recovered after similar treatments.

The hand's normal bacterial flora was quite recalcitrant to washing with water or soap. In many cases, the number of organisms recovered from fingers after washing was higher than that before washing (Table 2). Use of the hand sanitizer reduced the number of bacteria recovered to about 2 to 8% of the initial count.

Recovery of pathogens from gloves

Three types of gloves, all approved for food handling, were tested. Ten microliters containing 60 to 600 CFUs of each pathogen were inoculated onto each of four fingertips (excluding the thumb) of a glove and incubated at room temperature for up to 40 minutes, or until the inoculated areas were visibly dry. To estimate the potential for pathogen transfer from gloves, fingertips of each glove were touched on the surface of an agar plate. The touched area was spread and incubated as described above.

Initial trials (data not shown) indicated that the percent of inoculum recoverable from the glove fingertips decreased gradually with incubation time, with a sharp decrease in CFUs when the gloves dried. The inoculated areas on three brands of gloves tested all dried at different rates. Brand A dried the fastest with an average drying time of 3 1 minutes, whereas brand B, which had a rough surface texture, had the longest average drying time of 63 minutes (Table 3). Brand C gloves had an intermediate drying time of 43 minutes.

The percent of inoculum recovered (or potentially transferable) from gloves immediately after inoculation ranged from 53 to 80%. After 40 minutes, the lowest recovery (5 to 10%) was obtained from brand A gloves, which were all completely dried. Brand B gloves, which were all still visibly moist, had recovery levels ranging from 24 to 53%. After brand B gloves were completely dried, the recovery decreased to 4 to 10%, which is comparable to that obtained with the other two brands when dried.

The number of organisms obtained from inoculated glove fingertips touched successively to two separate agar plates indicated that about 80% of the inoculum could be recovered from the first two touches immediately after inoculation (Table 4).

Summary

For the pathogens tested in this study, the rate of drying appeared to be a major factor in affecting the number of organisms recoverable from hands or gloves. Drying substantially decreased the recovery levels. Inocula on hands dried much more quickly than on gloves, and 2 to 10% of the inoculated organisms were recovered after only 2 minutes. Depending on the glove texture, gloves may remain visibly moist 40 minutes after inoculation, in which case a much higher percentage (24 to 53%) of the inoculum could still be recovered. Washing with water, soap, or hand sanitizer was quite effective in inactivating or removing most of the pathogens inoculated onto fingers. S. *aureus* and *B.* cereus, both Gram positive organisms, were slightly more resistant to washing than the two Gram negative pathogens tested. The normal bacteria flora was very recalcitrant to removal by soap and water, but could be reduced substantially with the hand sanitizer.

Table 1. Percent recovery of pathogens from fingers after various hand washing procedures.

		% inoculum recovered after washing with:		
Pathogen	No wash	Water	Soap	Hand sanitizer
S. en teritidis	10.2	0	0	0
E. coli O157:H7	8.1	0	0	0
S. aureus	10.3	0.8	3.6	0.2
B. cereus	2.3	0.4	0.3	0.8

Table 2. Recovery of normal flora from fingers after various handwashing procedures.

	CFU recovered per subject					
	Water		Soap		Hand sanitizer	
Subject	Before	After	Before	After	Before	After
1	217	649	126	395	120	10
2	259	480	466	259	1029	18
3	85	282	126	270	216	4
4	308	194	287	138	418	13
5	236	339	93	202	240	5

Table 3. Percent recovery of pathogens from gloves at different times after inoculation.[a]

Pathogen	Time after inoculation	% inoculum recovered from glove		
		A	B	C
S. enteritidis	0 min	64.0	77.0	80.2
	40 min	5.4	53.2	10.3
	After dried	10.0	9.7	8.7
E. coli O157:H7	0 min	59.6	66.5	61.7
	40 min	10.4	33.9	19.1
	After dried	9.8	9.7	13.5
S. aureus	0 min	54.8	52.9	57.5
	40 min	5.2	23.6	6.0
	After dried	8.3	7.9	4.3
B. cereus	0 min	62.6	58.0	60.1
	30 min	4.6	45.2	26.2
	After dried	4.8	4.4	4.0
	Average drying time	31 min	63 min	43 min

[a]A, B, and C represent separate brands.

Table 4. Percent recovery of pathogens from gloves at each of two successive touches.

Pathogen	Minutes after inoculation	Touch #	% inoculum recovered from glove		
			A	B	C
S. aureus	0	1	55.9	55.9	48.4
		2	20.9	22.6	21.5
	40	1	2.9	33.8	2.4
		2	1.4	23.6	2.1
E. coli O157:H7	0	1	66.0	57.3	59.4
		2	21.0	20.1	23.9
	40	1	11.4	31.4	17.9
		2	3.3	20.1	4.6

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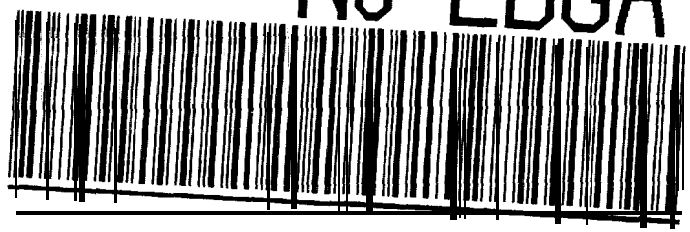

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